DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 28, 2015

Exactech, Incorporated
% Kenneth Maxwell
Regulatory and Quality Specialist
Empirical Testing Corporation
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K150130
Trade/Device Name: Ascendant™ Cervical Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: April 27, 2015
Received: April 28, 2015

Dear Mr. Maxwell,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K150130

Device Name
Ascendant™ Cervical Spacer System

Indications for Use *(Describe)*

The Ascendant™ Cervical Spacer System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease at one disc level from C2-T1. Degenerative Disc Disease (DDD) is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Ascendant™ Cervical Spacer System is to be used with autogenous bone graft and supplemental fixation (i.e., an anterior cervical plate), and is implanted via an open, anterior approach. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

Type of Use (Select one or both, as applicable)
☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

PSC Publishing Services (301) 443-6740 EF

510(K) SUMMARY

Submitter's Name:	Exactech
Submitter's Address:	2320 NW 66th Court Gainesville, FL 32658
Submitter's Telephone:	352.377.1140
Contact Person:	Kenneth C. Maxwell Empirical Testing Corp. 719.291.6874
Date Summary was Prepared:	28 April 2015
Trade or Proprietary Name:	Ascendant™ Cervical Spacer System
Common or Usual Name:	Intervertebral Fusion Device With Bone Graft, Lumbar
Classification:	Class II per 21 CFR §888.3080
Product Code:	ODP
Classification Panel:	Orthopedic

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Ascendant™ Cervical Spacer System is an anterior cervical interbody device consisting of a PEEK Optima® LT1 (polyetheretherkeytone) implant cage with CP titanium coating and tantalum radiographic markers. It is intended for use as an interbody fusion device and is offered in a variety of heights, footprints and lordotic angles to accommodate varying anatomical conditions. The device features an enclosed chamber intended to be filled with autogenous bone graft material.

The Ascendant™ Cervical Spacer System is intended to be used with supplemental fixation (i.e., an anterior cervical plate).

INDICATIONS FOR USE

The Ascendant™ Cervical Spacer System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease at one disc level from C2-T1. Degenerative Disc Disease (DDD) is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Ascendant™ Cervical Spacer System is to be used with autogenous bone graft and supplemental fixation (i.e., an anterior cervical plate), and is implanted via an open, anterior approach. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

The indications for use for the Ascendant™ Cervical Spacer System, Ti Coated is identical to that of the Exactech Cervical Spacer System (K141129).

TECHNOLOGICAL CHARACTERISTICS

The subject device is identical to the primary predicate with the exception of the subject device being Ti coated.

Table 5-1 Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Type
K141129	Cervical Spacer System	Exactech	Primary
K123909	CeSpace XP Intervertebral Body Fusion System	Aesculap	Reference

PERFORMANCE DATA

The Ascendant™ Cervical Spacer System, Ti Coated has been tested in the following test modes:

- Static Compressive Shear per ASTM F2077
- Static Expulsion per ASTM F-04.25.02.02
- Dynamic Axial Compression per ASTM F2077
- Dynamic Compressive Shear per ASTM F2077
- Dynamic Torsion per F2077
- Percent Porosity per ASTM F1854-09
- Coating Thickness per ASTM F1854-09
- Static Shear per ASTM F1044-05
- Static Tensile per ASTM F1147-05
- Shear Fatigue per ASTM F1160-05
- Abrasion per ASTM F1978-00

The results of this non-clinical testing show that the strength of the Cervical Spacer System, Ti Coated is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Ascendant™ Cervical Spacer System, Ti Coated is substantially equivalent to the predicate device.